

## DISTRICT OF MINNESOTA

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)  
) File No. 15-MD-2666  
) (JNE/FLN)  
)  
) February 27, 2017  
) Minneapolis, Minnesota  
) Courtroom 9W  
) 11:00 a.m.  
)  
)

(PLAINTIFFS' MOTION TO OVERRULE VITAHEAT MEDICAL, LLC'S  
RELEVANCY OBJECTION SO SUBPOENA)

FOR THE PLAINTIFFS:

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## P R O C E E D I N G S

(10:59 a.m.)

THE COURT: So this is the plaintiff's motion to overrule VitaHEAT Medical, LLC's, relevancy objection to subpoena. Let's get everybody's appearance on the record. For the plaintiffs?

MR. SACCHET: Michael Sacchet for plaintiffs.

MR. HULSE: Ben Hulse speaking for both 3M and VitaHEAT, and with me is Deborah Lewis who is also separately representing VitaHEAT.

THE COURT: Okay. And also at plaintiff's table is?

MS. ZIMMERMAN: Yes, Your Honor. Genevieve Zimmerman for plaintiffs as well.

THE COURT: Let me make sure I'm understanding the procedural posture. So plaintiffs have served a subpoena on VitaHEAT for a bunch of documents?

MR. SACCHET: That's correct.

THE COURT: And they have not provided any and instead objected to your document description attached to the subpoena?

MR. SACCHET: That is correct, Your Honor.

THE COURT: So this is, I would have used the vocabulary of a motion to compel them to produce the documents?

1 MR. SACCHET: I think that's correct in part,  
2 although there are some outstanding issues that plaintiffs  
3 have not necessarily briefed regarding the issues of the  
4 burdensomeness, and the confidentiality concerns that  
5 VitaHEAT has, so we did stylize the motion --

6 THE COURT: So even if I do overrule the  
7 objection, it doesn't mean that they're going to produce the  
8 documents? That's what you stood up for.

9 MR. HULSE: That's correct, Your Honor.

10 THE COURT: Never mind then, have a seat. I think  
11 I've got it.

12 MR. HULSE: All right.

13 THE COURT: Go.

14 MR. SACCHET: Good afternoon, Your Honor. We  
15 appreciate your time in hearing this motion today regarding  
16 plaintiffs' motion to overrule VitaHEAT's relevancy  
17 objection. Before I delve into the doctrinal framework by  
18 which I believe the Court should analyze the legal question  
19 as to whether the UB3 manufactured by VitaHEAT is an  
20 alternative design to the Bair Hugger, I'd like to present  
21 two very important facts for the Court's consideration and  
22 which should be kept in mind as we discuss these issues this  
23 afternoon.

24 The first of those facts is this, and one that  
25 plaintiffs made clear in their submission to the Court. The

1 510(k) predicate device of the UB3 is the HotDog patient  
2 warming device. The very device that 3M at virtually every  
3 step of this litigation has attempted to seek discovery of.  
4 In fact as you're aware, 3M brought a motion to compel with  
5 respect to documents pertaining to the HotDog.

6 THE COURT: Which was denied.

7 MR. SACCHET: Which was denied, you're correct,  
8 Your Honor. However, the Court's Order as to that  
9 particular issue denied discovery as to the HotDog because  
10 plaintiffs had not alleged or represented to the Court that  
11 the HotDog was in fact an alternative design to the Bair  
12 Hugger. That is not the case now in light of plaintiff's  
13 submission to the Court in which we maintain that the UB3 is  
14 an alternative design to the Bair Hugger, and I represent to  
15 you that today as an officer of this court that that is in  
16 plaintiffs' position.

17 THE COURT: And you've produced all of the  
18 documents that I denied the motion to compel about?

19 MR. SACCHET: We have discussed your Order on  
20 November 23rd with VitaHEAT's counsel as to your basis for  
21 the denial of the motion to compel, but we don't believe  
22 that it's apposite with respect to the circumstance now  
23 before the Court.

24 THE COURT: So if I grant your motion today, I  
25 would need to revisit the order I entered in November.

1           MR. SACCHET: I don't think that you would  
2           necessarily need to do that, Your Honor, because we have not  
3           maintained that the HotDog is an alternative design to the  
4           Bair Hugger. We are simply maintaining that the UB3 at this  
5           point among other conductive fabric forming devices,  
6           including one produced and manufactured by other companies  
7           such as Gaymar and Medline, which are not Augustine  
8           Biomedical in design, follows our alternative design to the  
9           Bair Hugger.

10           So we do not believe in fact that you would need  
11           to revisit that Order, although you could. At bottom, we  
12           believe that in light of your Order, you had represented  
13           that plaintiffs had not alleged that the HotDog was an  
14           alternative design, that's why discovery was denied as to  
15           the Bair Hugger, but that is not the case today with respect  
16           to the UB3. And this is one of the reasons why we believe  
17           that the UB3 is an alternative design to the Bair Hugger.

18           In our papers, we had described that the 510(k)  
19           predicate device of the UB3 is the HotDog. One fact that we  
20           did not make clear in our papers and which we did not have  
21           an opportunity to present in a reply brief given the local  
22           rules is that the 510(k) predicate device of the HotDog is  
23           the Bair Hugger 750. So to the extent that VitaHEAT and 3M  
24           are arguing that the UB3 is a substantially different  
25           product that uses a substantially different technology, we

1 believe that that's belied by the submissions to the FDA and  
2 the FDA's conclusion that the Bair Hugger is substantially  
3 equivalent to the HotDog, and the HotDog is substantially  
4 equivalent to the UB3, because all share the same intended  
5 use, and all share similar technological characteristics,  
6 and that is one fact that not a single case that 3M or  
7 VitaHEAT have cited in their papers attacks or deals with.

8 In fact, In Re: Mentor Corp., which is a case that  
9 we have cited in our papers in which an MDL court confronted  
10 the question as to whether two devices that were  
11 substantially equivalent were relevant to discovery, and in  
12 3M's words as they say in their papers, the Court quickly  
13 moved past the issue of relevance because the two devices  
14 were substantially equivalent. In plaintiffs' view, that  
15 proves the point, and the Court need not even go any further  
16 as a matter of Rule 26(b)(1), and the threshold showing of  
17 relevance that plaintiffs must meet in order to obtain  
18 discovery as to this device.

19 Moreover, and back to your original question, Your  
20 Honor, 3M maintained when conducting discovery about the  
21 HotDog that had plaintiffs alleged that the HotDog was an  
22 alternative design, that discovery as to conductive warming  
23 devices would be at the core of this case. That's precisely  
24 that's occurred here. Plaintiffs maintain that the UB3 is  
25 an alternative design to the Bair Hugger, and thus in 3M's

1 worries, we believe that such discovery is at the core of  
2 this case.

3 THE COURT: I'm sorry, at the core of is a quote  
4 from my Order or a quote from some other case?

5 MR. SACCHET: It is actually a quote that was used  
6 in 3M's motion to compel with respect to the Augustine's  
7 documents that can be found at docket number 130 on page 37.

8 THE COURT: What's the most I said in my Order?

9 MR. SACCHET: So in your Order, Your Honor, you  
10 cite Mr. Blackwell's representation at the November 17th  
11 hearing that something to the extent of had plaintiffs  
12 identified the Bair Hugger, that that discovery would be at  
13 the core of the case. So you have a mirroring parenthetical  
14 cite to that representation in your Order, but you denied  
15 that Order because you used the conditional if clause  
16 because plaintiff had not yet made that representation.

17 THE COURT: About the Bair -- about the HotDog?

18 MR. SACCHET: About the HotDog, not as to the UB3.  
19 So those are the critical facts that I'd like the Court to  
20 keep in mind. And in terms of the doctrinal framework,  
21 based on my review of the cases, I believe that there are  
22 three buckets of cases, if you will, as to how a court might  
23 analyze an alleged alternative design.

24 In 3M and VitaHEAT's view, in order for an  
25 alternative design to exist, it must exist in what I'll

1 "bucket one," which is essentially a minor modification to  
2 an existing product. And they further maintain that  
3 plaintiffs' representation that the UB3 is an alternative  
4 design to the Bair Hugger fits in what I'll call the third  
5 bucket of cases, which deals with substantially different  
6 products. And then there's a second bucket of cases, which  
7 I'll describe in a moment.

8 With respect to the first bucket, I don't think  
9 there's a dispute that a modification to the Bair Hugger in  
10 terms of adding a HEPA filter, let's say, to the current  
11 filtration of the device, which scientific studies show are  
12 only capable of filtering approximately 50 to 60 percent of  
13 particulates at .2 microns could be improved by a HEPA  
14 filter, and that would be a type of minor modification in  
15 plaintiffs' view that fits in bucket one because it's the  
16 same product and a minor modification to that product.

17 In terms of the third bucket of cases, and those  
18 are the cases that are filled in 3M's brief, those involved  
19 circumstances such as the *Caterpillar* case out of Texas when  
20 the Court mused, well, let's talk about a motorcycle. Would  
21 adding two wheels to a motorcycle still render the vehicle a  
22 motorcycle, a quad motorcycle? Of course not. The  
23 essential characteristic of the motorcycle is easily lost by  
24 the addition of two wheels rendering it just a four wheel  
25 automobile, and the other cases follow suit.



1           So, for example, they cite *Massa*, another case out  
2           of Texas, for the proposition that federal and state courts  
3           across the country have consistently held that plaintiffs  
4           cannot demonstrate the existence of a safer alternative  
5           design by pointing to a substantially different product.

6           Now, I want to dissect *Massa* just very briefly.  
7           In *Massa*, the plaintiff alleged that a biologic medication  
8           called Raptiva, which is used to treat a skin disease called  
9           psoriasis, was defective because it led to various  
10          externalities. As an alternative design, the plaintiffs  
11          there alleged that other conventional treatment, such as  
12          topical cream and UV light treatments could be an alleged  
13          alternative design. Those are entirely different products,  
14          and it's not surprising that the Court there held as much.

15          The same applies to *Tersigni*, which is the First  
16          Circuit case that 3M cited there, just like in *Massa*, the  
17          plaintiff alleged that a weight loss drug called Pondimin  
18          was defective and that an alleged alternative design  
19          involving unrelated "methods of weight loss", were the  
20          alternative design. I mean those could range from diet,  
21          exercise, don't even involve products. So, again, there it  
22          is unsurprising that the Court found that those alternatives  
23          were not alleged alternative design. And I should also add  
24          that that was on summary judgment, not a Rule 26(b)(1)  
25          determination of relevancy.

1           Moreover, in *Theriot*, the Fifth Circuit case,  
2           which is a per curiam decision, it does not hold  
3           precedential weight, analyzed whether a system of pedicle  
4           screws in plates used during a back surgery could be an  
5           alternative design to a system of neck braces. Again, an  
6           entirely different product or a hook and wire system, which  
7           again is a different product.

8           So when 3M uses the term "substantially different"  
9           on virtually every page of their submission, that means  
10          something. They cannot walk away from the idea that an  
11          alleged alternative design can and in fact does exist in  
12          numerous cases involving other products. And, indeed, some  
13          of the cases that we cited in our first submission and a few  
14          additional cases that I'd like to discuss this afternoon  
15          prove that point.

16          THE COURT: You're going to be done this morning.

17          MR. SACCHET: Oh, I apologize. I was treating  
18          11:00 as afternoon, but in any case, I respect that.

19          So one such case, which we did discuss in our  
20          papers, was *Security National Bank of Sioux City v. Abbott*  
21          *Laboratories*. And in that case, Judge O'Brien, who was the  
22          District Court Judge from the Southern District of Iowa,  
23          considered whether a liquid baby formula versus a solid baby  
24          formula were alternative designs. And just like here, in  
25          that case, the defendant cited *Burks*, an opinion authored by

1 Judge Tunheim, for the proposition that different products  
2 can't be an alternative design.

3 Judge O'Brien readily dispensed with that argument  
4 reasoning that the measure of similarity of two products  
5 when determining whether an alternative design exists is  
6 inexorably related to the purposes for which the products  
7 are used, and the judge refused to draw what he said to be a  
8 magic line of demarcation separating an alternative product  
9 from an alternative design; and, therefore, denied the  
10 defendant's motion to dismiss on the ground that the issue  
11 should be discoverable and dealt with on summary judgment.

12 Other cases even in this district have made  
13 similar declarations. So, for example, in *Block v. Toyota*,  
14 I realize that the factual underpinnings of that case  
15 involve a 1996 Camry and a 2000 Camry, and 3M makes it clear  
16 that it's the same type of model car. However, Judge  
17 Montgomery was very clear in stating when a safer  
18 alternative design has been implemented in other products,  
19 the jury may consider the other products in determining  
20 feasibility and safety.

21 Other district courts across the country have come  
22 to the same conclusion. For example, a case *Sisk*, which can  
23 be found at 2012 Westlaw 3155586, the Western District of  
24 North Carolina; along with *Newman* at 2013 Westlaw 7217197,  
25 out of the Northern District of Illinois. Those are just a

1 sampling of the cases that I've found that other products  
2 can be alternative designs.

3 What I do want to focus on for a minute, however,  
4 is an Eighth Circuit case, and we did not have an  
5 opportunity to present this under the local rules, excluding  
6 us from filing a reply, which we respect. However, for the  
7 sake of argument today, this opinion is entitled *Lauzon v.*  
8 *Senco Products*. This can be found at 270 F.3d 681. It's an  
9 opinion authored by Judge Lay.

10 In that opinion, the plaintiffs alleged that what  
11 was called a bottom fired nail gun was defective because it  
12 fired when the user did not attempt to fire the gun. The  
13 way a bottom-fire nail gun works is you depress the trigger,  
14 and you simply tap the bottom of the nail gun on a flat  
15 surface, and it automatically fires nails. In alleging an  
16 alternative design, the plaintiff claimed that what's called  
17 a sequential-fire nail gun could be an alternative design.

18 And the way that a sequential-fire nail gun works  
19 is you must be contrast to a bottom-fire nail gun manually  
20 depress the trigger every time you want a nail to be  
21 deployed. The district court in that case granted summary  
22 judgment to the defendant and excluded the plaintiffs'  
23 expert on Daubert grounds.

24 Judge Lay on behalf of the panel reversed the  
25 district court and found that the expert had an appropriate

1 methodology and expertise to declare that the bottom-fire  
2 nail gun was an alternative design to the sequential-fire  
3 nail gun, notwithstanding the technological differences  
4 between the two guns. They both fired nails. That's a case  
5 that we believe is controlling here and would run head long  
6 into 3M's argument and VitaHEAT's argument.

7 But at bottom, Your Honor, a number of facts here  
8 in light of those cases we believe do prove as a matter of  
9 law that the UB3 is an alternative design. And those facts  
10 again include, one, the substantial equivalence under the  
11 510(k) filing linking the Bair Hugger to the HotDog and the  
12 UB3, notwithstanding the fact that the Bair Hugger uses  
13 convection warming, whereas the HotDog and the UB3 uses  
14 conductive warming. That's the determination that's been  
15 made by the FDA.

16 And in fact, in the FDA filing, all of these  
17 products are deemed thermal regulation systems. They're not  
18 deemed thermal convective systems or thermal conductive  
19 systems. They're just thermal regulation systems used for  
20 patient warming.

21 Another fact to keep in mind, on 3M's website to  
22 this very day, and if you go on it, the Bair Hugger is not  
23 advertised as a conductive convective warming system.  
24 Quoting from their website, it's a therapy temperature  
25 management unit or just a warming unit. Nothing

1 distinguishes it technologically from other units. I  
2 suppose if you go on the web page and you dig deep, you'll  
3 find some mention to convective technology. But on the face  
4 of the page, that's how it's presented, and the same goes  
5 for the UB3.

6 Again, there are mentions in, you know, subsequent  
7 tabs that it's a conductive warming, but on the face of the  
8 representation, it's a warming device, and both devices  
9 share that representation.

10 Moreover, as I've mentioned and as our papers  
11 show, numerous 3M employees have referred to for over two  
12 decades the intent to develop an air-free alternative to the  
13 Bair Hugger, and that's been a constant refrain by employees  
14 of the company since well before 2000, and our exhibits to  
15 our submission make that clear.

16 In addition to those facts, we have taken numerous  
17 depositions of 3M employees, and we've attempted to ask  
18 those employees about the VitaHEAT and the UB3, and on not  
19 one occasion has 3M objected to the relevance in questions  
20 as they appear to do now with respect to our discovery  
21 requests.

22 Finally, there are a number of scientific studies  
23 that have even been conducted by 3M's key opinion leaders,  
24 namely, Dr. Sessler and Dr. Kurz, who have published some of  
25 the most monumental studies in the field on these topics.

1 And many of those studies directly compare the Bair Hugger  
2 to other conductive warming devices. And in fact, one such  
3 study authored by Dr. Sessler entitled, "A Randomized  
4 Comparison of Intraoperative PerfecTemp and Forced Air  
5 Warming During Open Abdominal Surgery," refers to the  
6 conductive warming device as an alternative to the Bair  
7 Hugger.

8 Now, I realize that Dr. Sessler's representations  
9 are not legal representations. However, it would be curious  
10 indeed if all of these authors were comparing apples and  
11 oranges as opposed to apples and apples, and that's part of  
12 the reason why we believe that the UB3 is an alternative  
13 device to the Bair Hugger.

14 And one other fact to keep in mind, both the UB3  
15 and the Bair Hugger use blankets to maintain patient  
16 normothermia. These are not devices that use intravenous  
17 blood warming or that use passive insulation or that use  
18 humidification or that use UV light treatment, which are  
19 found in other products on the market to maintain patient  
20 normothermia. Both of these products have a device  
21 connected by a cord or a tube to a blanket and that blanket  
22 is either put on top of the patient or under the patient in  
23 order to warm the patient. So in terms of the usability of  
24 the product, that goes to why they're substantially  
25 equivalent and the FDA found the same.

1           Now, I'd like to have a few more words on the  
2           procedural posture of this case.

3           THE COURT: You have about three seconds. So in  
4           five minutes, you need to be done.

5           MR. SACCHET: Okay, five minutes.

6           As the Court knows, this is a matter of a  
7           discovery request under Rule 26(b)(1), this Court's prior  
8           opinion, namely, in *Coleman* have made that standard clear by  
9           noting that relevancy should be broadly construed. The  
10          sentence directly from your opinion reads, "relevancy means  
11          any matter that bears on or that reasonably could lead to  
12          other matters that could bear on any issue that is or may be  
13          in the case."

14          Clearly, this is an issue that plaintiffs believe  
15          is at issue, let alone it certainly may be at issue in this  
16          case given plaintiffs' burden under many state laws to prove  
17          an alternative design and the law and the facts that we've  
18          raised today at argument. And I would also like to mention  
19          that essentially all of defendant's cases, every single one  
20          of them does not deal with a discovery dispute. They all  
21          deal with dispositive motions. Many of them even recognize  
22          such as *Tingle v. Reynolds Tobacco*. That what constitutes a  
23          feasible alternative design, and what constitutes an  
24          entirely different product should be left to the jury.

25          So that determination need not be made by the



1 Court if it does not wish to. It's a question of law that  
2 we believe we can prove at summary judgment. But in terms  
3 of this dispute, even the cases that they rely on like  
4 *Burks*, Judge Tunheim there was concerned whether the two  
5 products were alternative design, but he nonetheless denied  
6 the motion to dismiss and left it for discovery and summary  
7 judgment to make that call.

8 So defendant's reliance on Al Van Duren's  
9 declaration is well outside the pleadings and introduces  
10 facts that we have not had an opportunity to investigate nor  
11 discuss. And under their statement curative tort section F,  
12 plaintiffs quote, "should have an opportunity to conduct  
13 reasonable discovery so as to ascertain whether an  
14 alternative design is practical."

15 So that's really the landscape of our relevancy,  
16 and I respect the Court's time. And to the extent that  
17 proportionality and confidentiality concerns come up by 3M,  
18 I do have things to say on that. I do very quickly note  
19 that we don't believe it's ripe. We do believe our requests  
20 are similar in nature to the requests that 3M served on  
21 Augustine. We are willing to narrow our requests and work  
22 with 3M to cut down on the scope of any concerns that they  
23 might have and continue to meet and confer on them.

24 We also note that Augustine Biomedical is just as  
25 small of a company as VitaHEAT, but they've been subject to

1 numerous special discovery requests. The only difference is  
2 that we're not relying on Augustine Biomedical anymore, and  
3 we've made that very clear to the Court, whereas 3M has an  
4 ongoing relationship with VitaHEAT.

5 And, finally, as to confidentiality concerns, 3M  
6 has a blanket statement that says the protective order does  
7 not protect or preserve these documents to the extent that  
8 they would be marked confidential by VitaHEAT. I don't  
9 understand paragraph 7C 1-4 expressly provides for the  
10 protections that are given to documents that could involve  
11 competitive witnesses, so I think that objection is  
12 baseless.

13 So for those reasons, Your Honor, we request that  
14 the Court overrule VitaHEAT's relevancy objection.

15 THE COURT: Okay. Thank you. Mr. Hulse?

16 MR. HULSE: I'm speaking on behalf of both  
17 VitaHEAT and 3M on this relevance issue. And my colleague  
18 Ms. Lewis also from my firm but specifically represents  
19 VitaHEAT with respect to the burden issues, and with Your  
20 Honor's permission, she would speak on those.

21 Just a quick word on the posture. We did not  
22 agree to this relevance issue being brought ala carte to the  
23 Court. As Your Honor knows, 26(b)(1), there is the  
24 threshold relevance requirement. We don't believe it's met,  
25 but there's also the balancing test between relevance and

1       burden.

2               Two, and the point that we made to the plaintiffs  
3       in the meet and confer is even if you are able to prevail on  
4       relevance, and we don't think you do, you still have to  
5       overcome these burden objections too. And they're very  
6       serious burden objections given that they're asking for  
7       virtually every document from a 11-employee company within a  
8       very short time frame. And so we just don't think it was  
9       proper to bring this motion in this posture, and we made  
10      that clear in the meet and confer. That's one thing.

11             Another thing, too, that Your Honor should know is  
12      that this is just the tsunami on the horizon of third party  
13      discovery issues that are likely to come before the Court.  
14      In addition to this subpoena, the plaintiffs last week sent  
15      out five subpoenas to other manufacturers of patient warming  
16      devices, some of whom are some of the biggest medical device  
17      companies. And, of course, asking them to produce  
18      essentially all of their design, testing, marketing,  
19      regulatory communications, provider communications within  
20      the next two weeks. And so we've objected to that on the  
21      same relevance grounds, and I'm sure they will have  
22      objections to it too, these other manufacturers.

23             So what the Court does here will obviously have  
24      some impact on those fights to come that apparently will  
25      need to happen within the next three weeks given the general

1 causation fact discovery cut-off.

2 But turning to this relevance argument, Your  
3 Honor, I would just mostly refer you to the pages 10  
4 through 16 of our brief, where we go through the very, very  
5 long list of cases, overwhelming authority from  
6 jurisdictions throughout the country including this one that  
7 all come to the same point, which is that a different  
8 product doesn't legally qualify as a feasible, safer  
9 alternative design.

10 What the case law from across the country makes  
11 clear is what you need to do legally to meet that standard  
12 is have a modification to the existing product. And the  
13 cases that the plaintiffs cite overwhelmingly just support  
14 that point and certainly all the cases that we've cited  
15 support it too.

16 Why are these substantially different products?  
17 So, first off, let me explain to you briefly who VitaHEAT  
18 is, what the UB3 is, and what this relationship is with 3M.  
19 So for years, 3M has been looking to develop on its own or  
20 to enter into a partnership with a medical device that could  
21 be used in mobile settings, a warming device that could be  
22 used in mobile settings. The 3M Bair Hugger system requires  
23 being connected to an AC power source, and so it's  
24 restricted to the operating room.

25 So, obviously, you might want to have patient

1 warming when you're moving in the hospital. You might want  
2 to have it in the ambulance. You might want to have it in  
3 the helicopter, so you have to have a patient warming system  
4 that can run on batteries.

5 And so 3M identified the VitaHEAT UB3 system as a  
6 system that could run on batteries and, therefore, entered  
7 into a distributor agreement with the VitaHEAT system. It's  
8 not an acquisition. 3M doesn't own this product but a  
9 distribution agreement to distribute this product. And as  
10 the company said in their public statement announcing this  
11 near the end of last year, it was as a compliment to the  
12 Bair Hugger system, a mobile offering that could be used by  
13 health care providers when they're transporting patients.

14 THE COURT: But 3M is the exclusive distributor  
15 for this?

16 MR. HULSE: It is the exclusive distributor,  
17 exactly, Your Honor. So but the Bair Hugger system and the  
18 VitaHEAT UB3 use fundamentally different types of warming.  
19 Like the HotDog, the VitaHEAT UB3 is a conductive warming  
20 technology. And what basically it does is it uses a heating  
21 element powered by electricity to then conduct heat through  
22 a mattress and then the mattress glides under the patient.

23 THE COURT: But you asked for this exact same  
24 information from them, correct?

25 MR. HULSE: Yes.

1 THE COURT: And is your footnote to your mea  
2 culpa? Sorry, I didn't mean it. Just forgot.

3 MR. HULSE: It is our mea culpa, Your Honor, yes.  
4 I want to point out that our main justification for seeking  
5 HotDog related information from Dr. Augustine had to do with  
6 bias, but we did separately also say alternative design  
7 because we believed that the plaintiffs were seeking that.

8 As we looked at the case law more closely in  
9 response to this subpoena, it was clear that we were wrong  
10 to articulate alternative design as a basis. And,  
11 frankly --

12 THE COURT: But that was the basis that I bought,  
13 right? And I agreed with you that they haven't said that,  
14 therefore, it's not relevant. Therefore, you don't get it.

15 MR. HULSE: That's true, Your Honor. And in fact  
16 when Mr. Blackwell argued, he set aside that argument at the  
17 hearing too because even at that point, we were seeing that  
18 it didn't seem like a very strong argument. We dug in more  
19 to the case law afterwards, and it was clear to us that  
20 legally we were not right to pursue that.

21 So we think that Your Honor not only was correct  
22 to say that there shouldn't be discovery on the HotDog on  
23 the basis of them not identifying it as a feasible safer  
24 alternative design, but also if they had identified it as a  
25 feasible safer alternative design, discovery wasn't proper

1 on that basis.

2 We still thought that discovery should, their  
3 alternative bases for discovery having to do with bias.  
4 Here the only basis that plaintiffs have articulated for the  
5 discovery is feasible safer alternative design. And so the  
6 VitaHEAT system, as I said, is a conductive warming  
7 technology. The 3M Bair Hugger system is convective, and it  
8 uses temperature controlled air that then goes into the  
9 blanket and warms the patient through heat distribution  
10 through the perforations in the blanket.

11 And the declaration of Al Van Duren, the Director  
12 of Scientific Affairs at 3M and is also trained and familiar  
13 with the design of the VitaHEAT UB3 is straightforward.  
14 There's not only fundamentally different types of  
15 technology, you cannot integrate the conductive warming  
16 technology of the VitaHEAT or the HotDog for that matter  
17 into the Bair Hugger system without just simply turning it  
18 into the VitaHEAT UB3. It's substituting one product for  
19 another. And what the cases say over and over and over and  
20 over again is that a feasible safer alternative design is  
21 not an argument that the defendant should have just sold a  
22 different product. And that is essentially what the  
23 plaintiffs are arguing here. And, in fact, is what the  
24 plaintiffs are arguing here is that the Bair Hugger instead  
25 of selling the Bair Hugger, 3M should sell the VitaHEAT UB3.

1 I also want to point out that given that the  
2 VitaHEAT UB3's predicate device is the HotDog, it is in fact  
3 puzzling to figure out why the plaintiffs took no position  
4 on that when we were seeking discovery from Augustine but  
5 now have decided that every other conductive device, this  
6 and the other one that they've sought discovery from are  
7 safer alternative designs.

8 But, Your Honor, it comes down to the point that  
9 as a matter of law, the plaintiffs cannot show because of  
10 these fundamentally different technologies that the VitaHEAT  
11 UB3 is a feasible safer alternative device. It is not a  
12 matter of factual dispute. It is simply a matter of law.  
13 And that is why many of these cases as we've cited have  
14 granted motions to dismiss where other products that served  
15 the same purpose and here they clearly serve the same  
16 general purpose of warming, but other products were  
17 identified as feasible safer alternative designs. Courts  
18 have frequently granted motions to dismiss and that, I  
19 think, strongly leads, supports also denying discovery  
20 because discovery must be relevant. If something can get  
21 you -- gets tossed out on a motion to dismiss, also there  
22 shouldn't be discovery on it.

23 And I want to be very clear about what we do agree  
24 would be a feasible safer alternative design. Consistent  
25 with the *Bar Maid* case that Judge Ericksen decided and that



1 plaintiffs cited. A modification to the defendant's product  
2 that is being challenged, the plaintiffs can say this change  
3 should have been made to the product. This feasible change  
4 should have been made to the product to make it safer, then  
5 they have a legally viable basis to go forward.

6 But, here, they have come forward with no  
7 evidence, not an expert affidavit, not any testimony from 3M  
8 witnesses or anybody else that could establish -- and they  
9 can't -- that could establish that the 3M Bair Hugger system  
10 could be re-engineered to become a conductive warming device  
11 like the UB3.

12 So that's the legal point. I'm not -- we've  
13 distinguished all of their cases readily. In fact, I've  
14 rarely seen a discovery motion that was so weakly supported  
15 by case law as the ones here. They did not cite the *Lauzon*  
16 case in their opening brief, and if it was so important, I  
17 would have thought they would. But if the Court would like,  
18 we'd be happy to submit a supplement on the *Lauzon* case that  
19 was from the Eighth Circuit.

20 And with that, unless Your Honor has questions  
21 about the legal relevance issues, I would turn over to my  
22 colleague Ms. Lewis to talk about the burden issues.

23 THE COURT: You got about 30 seconds to talk about  
24 burden, I guess. Go ahead, but make it quick.

25 MS. LEWIS: Thank you, Your Honor. I think I can

1 be pretty short and to the point. The burden in this case  
2 for VitaHEAT is real, and let me reiterate those facts. It  
3 is a nonparty. It has nothing to do with this lawsuit. It  
4 has no connection to the lawsuit. It knew nothing about the  
5 lawsuit before plaintiffs sent the subpoena to them.

6 The declaration of Mr. Renwick, which is a part of  
7 our materials, goes into detail on why there would be a  
8 serious impact on VitaHEAT if it were required to produce.  
9 It would take 30 percent, nearly 30 percent of their work  
10 force to respond to it over a two to three week time period.  
11 That means Mr. Renwick, who would be in charge, would not  
12 then be able to do his normal responsibilities at the  
13 company.

14 VitaHEAT is a very small company. It was only  
15 formed in 2012. It has very few employees. It doesn't have  
16 in-house attorneys who could help. A lot of their documents  
17 are even not housed within the company. They would have to  
18 engage their outside partners to bring those documents  
19 together. But the fact that they would have to abandon  
20 their work, put nearly 30 percent of their work force to do  
21 this for a device that's not even relevant to the case, that  
22 is a completely different medical device than the Bair  
23 Hugger seems to be too much of a burden for a nonparty to  
24 respond to.

25 And the subpoena that was sent to Augustine being

1 a small company is nowhere -- they're night and day. The  
2 subpoena with Augustine, Augustine is connected all through  
3 this lawsuit. VitaHEAT is not. So it's not fair to make a  
4 comparison between the subpoena that was sent to Augustine's  
5 companies and the subpoena that plaintiff sent to VitaHEAT.

6 The competitive harm, Mr. Renwick also describes  
7 in his declaration. The most important one for Your Honor  
8 to consider is the fact that it is plaintiff's co-lead  
9 counsel who submitted or signed the subpoena. He is the  
10 either continuing or former counsel for Scott Augustine.  
11 VitaHEAT is extremely concerned about the risk of its  
12 documents, design documents, testing documents, research  
13 documents in this highly competitive medical device market.

14 THE COURT: But that's covered by the protective  
15 order, right? Don't we have a section that deals with  
16 precisely that issue?

17 MS. LEWIS: I don't believe that my interpretation  
18 of the protective order would cover VitaHEAT. The  
19 protective order talks about forced air warming devices, and  
20 it talks about Augustine. But it says, there's no remedy  
21 for a nonparty like VitaHEAT that is discussed in this  
22 protective order at all. And just the extreme concern how  
23 aggressive Dr. Augustine is with respect to competitors,  
24 they're extremely concerned being such a small new company  
25 to be at risk for what might happen to their documents,

1       whether they were inadvertently disclosed or not, for them  
2       to get into the hands of such an aggressive competitor.

3               THE COURT:   Okay.   Thank you.

4               MS. LEWIS:   Thank you.

5               THE COURT:   Anything else for the plaintiff?

6               MR. SACCHET:   I don't want to take much of your  
7       time, Your Honor.   I believe I used most of mine, but I  
8       would like to bring the Court just back to the fact that  
9       again this is a relevancy issue under Rule 26(b)(1).  
10      Plaintiffs must satisfy a threshold burden of relevancy,  
11      which the case law makes clear is an issue that may be or  
12      could be relevant to the case.   Clearly under most state  
13      law, the issue of an alternative design is one that  
14      plaintiffs must meet, and defendants in this case are likely  
15      alleging that there is no alternative design to the Bair  
16      Hugger that would have been safer than the accident product.  
17      So it's not only an issue that will need resolution, but  
18      it's one that their statement expressly allows for discovery  
19      upon in order for plaintiffs in this case to be able to  
20      truly evaluate whether the technological features of the UB3  
21      are something that is an alternative design, and whether  
22      Mr. Van Duren's "expert testimony" live up to what it says  
23      in the declaration that was filed in 3M's papers.

24              THE COURT:   So just answer this for me, so as I  
25      understood when you first stood up, you talked about three

1 buckets of cases. And you said those that are just  
2 modifications are clearly discoverable stuff because they  
3 are modifying an existing product for purposes of making it  
4 a safer design.

5 MS. SACCHET: Yep.

6 THE COURT: And then you talked about the third  
7 bucket, which is a whole new product, motorcycle, car, so  
8 talk to me, what are the cases that are in this second  
9 bucket?

10 MR. SACCHET: So in the second bucket of cases,  
11 these do involve circumstances in which there could be a  
12 different manufacturer of another product, so it's not a  
13 minor modification of the same product by the same  
14 manufacturer. And in those circumstances, the product has  
15 the exact same intended use of those products, and it likely  
16 has some differences.

17 So, for example, convective versus conductive in  
18 this case, but they share the same intent for use, the same  
19 purpose, usability, customer demand, appearance, all these  
20 things come together to say these products really aren't  
21 that different even though it's from a different  
22 manufacturer as opposed to a minor tweak of an existing  
23 product from the same manufacturer.

24 THE COURT: And why are -- okay, I think I got  
25 that. All right. Anything else?

1 MR. HULSE: No.

2 THE COURT: Anything else?

3 MR. SACCHET: That's it, Your Honor. I appreciate  
4 it.

5 THE COURT: All right. I'll take the matter under  
6 advisement, issue an order shortly, and we are in recess.

7 (Court adjourned at 11:39 a.m.)

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11 REPORTER'S CERTIFICATE

12 I, Maria V. Weinbeck, certify that the foregoing is  
13 a correct transcript from the record of proceedings in the  
14 above-entitled matter.

15

16 Certified by: s/ Maria V. Weinbeck

17 Maria V. Weinbeck, RMR-FCRR

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